



# Medicines for Ireland Policy Manifesto



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# Executive Summary

Medicines are now a key and increasingly important part of the treatment landscape for Irish patients. They are helping people live better and for longer.

The importance of medicines in our healthcare services is reflected in the amount we spend on them—15% of total health expenditure.

This depth of spend, and the need to continue to be able to meet the costs of ever more complex but effective medicines, requires all stakeholders to work together to guarantee access for Irish patients to the most innovative medicines at the most affordable prices.

This coherent approach necessitates significant reforms in how we use, fund and supply medicines to patients.

The publication of this policy document marks the official launch of a new healthcare representative body, Medicines for Ireland, a pharmaceutical-led organisation which is committed to reform in Irish healthcare and focused on enhancing the supply of and access to medicines for patients.



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For the first time, a coherent and strong movement for reform from within Ireland's medicine and pharmaceutical community has emerged to challenge the status quo and push for meaningful reforms which can improve outcomes for Irish patients.

Medicines for Ireland is aware of the challenges that exist right across our healthcare landscape. We strongly believe that there is an onus on all, not just political decision-makers, to bring forward, articulate and ultimately implement progressive and innovative reforms that can play a part in ensuring Ireland's health services are fit for purpose and capable of accommodating the fast-changing pace of medical and scientific advances.

A starting point for reform must be a National Medicines Strategy. This strategy will plot a clear vision for how medicines, particularly new medicines, can be delivered, supplied and funded to the benefit of Irish patients. Cost, access and funding of medicines are increasingly life-or-death decisions. Such decisions often occur in the absence of any joined-up thinking or long-term objectives. This haphazard approach must end.

For our part, we believe this policy paper, while in no way examining all healthcare and medicine issues, starts this much-needed reform conversation.

More importantly our paper sets out a number of key policy proposals which, if implemented in full, can make a significant contribution to addressing

issues such as affordability, access and equity in the supply of medicines. Our key policy proposals include:

- A National Medicine Strategy which sets out a long-term plan for medicine usage;
- Establishment of new National Medicines Office to implement this strategy;
- A radical reform of the Medicine Pricing Agreements, which set medicine prices, and are agreed between the Department of Health and pharmaceutical industry. These agreements must reflect the changed nature of the pharmaceutical industry and the erosion of distinctions between branded and generic medicines;
- A comprehensive roadmap to activate switching to more affordable but equally effective biosimilar medicines, thereby unlocking the potential for hundreds of millions in savings;
- Breaking down barriers to drive effective competition in the medicines market, through innovative pricing strategies; and
- Measures to tackle the growing problem of medicine shortages.

Change is always necessary and possible, but in Ireland we have been too slow to reform our approach to medicine procurement. Too often we only adapt and reform years or even decades after such changes are commonplace elsewhere. We cannot afford to do this when it comes to healthcare and medicine reforms.

The membership of Medicines for Ireland has a track record of reform, having been to the fore in the introduction and implementation of providing patients with more affordable medicines, particularly through generic substitution in recent years. We are eager to continue this reform momentum so that Ireland's medicine policy is fit for purpose and reflective of changes that are already well-embedded across the globe.

We urge all decision-makers to carefully examine the proposals herein, and to move to implement these reforms as a matter of urgency. The lives of patients and their continued access to the best quality of care is at stake.

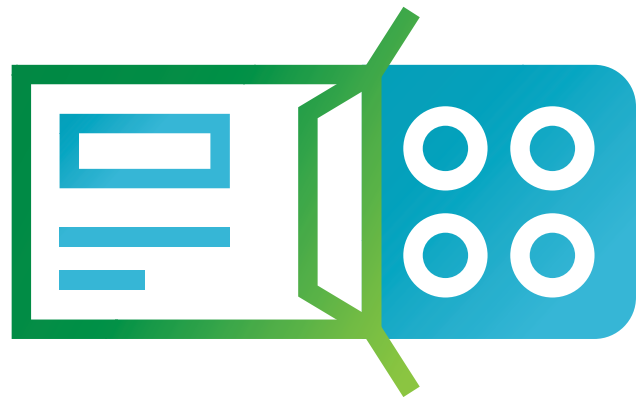


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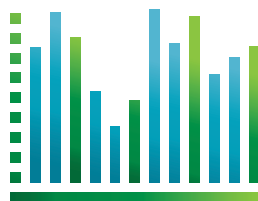
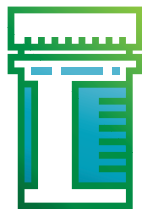


*Medicines for Ireland, July 2017*

# KEY FACTS & FIGURES

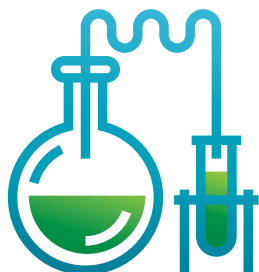






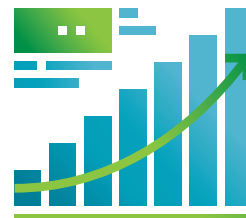
## 8th HIGHEST

Ireland ranks as the 8th highest health spend per capita amongst 35 OECD countries.



## DOUBLED COST

The State's spend on high-tech medicines has doubled in cost in seven years from €315 million in 2009 to €662 million in 2016.



## €62 BILLION

€62 billion worth of biologic medicines are expected to go off patent by 2020, but only 11 of the 23 biosimilars authorised by the European Medicines Agency are currently reimbursed by the HSE



## 14,157 vs 36

There is a lack of genuine competition between biologics and biosimilars in Ireland. In just one case Enbrel (biologic) sold 14,157 packs during May 2017, with its biosimilar equivalent Benepali selling just 36



## €14.6 BILLION

In 2017, Ireland will spend €14.6 billion on health, an increase of almost one billion since 2016.

## €2 BILLION

Total spend on medicine in 2015 by the HSE was €2 billion – the largest single item in the healthcare budget.



## 18.4% OVER 60

18.4% of the population is now over 60, with this figure expected to reach 1.15 million by 2026.

## 140 MEDICINES OUT OF STOCK

Medicines shortages are increasing, with over 140 medicines currently out of stock in Ireland.





## Our Vision

  
*Our vision is  
that all Irish  
patients can  
afford and  
access the  
medicines  
they need to  
get well,  
stay well  
and live well.*



The foundation of Medicines for Ireland represents the coming together of Ireland's leading pharmaceutical companies as a cohesive, change-oriented organisation focused on achieving positive reforms in the Irish health service.

Collectively and individually we have a wealth of Irish and international expertise in the supply and delivery of medicines to patients, through the tens of millions of medicines packs we supply to Irish patients each year and more broadly through our global parent companies.

We believe that our health services can and must perform and deliver better for patients than is currently the case.

We hope with this experience, we can be a key partner of Government, our health service and patients to achieve better outcomes and the highest quality of care.

Our vision is that all Irish patients can afford and access the medicines they need to get well, stay well and live well.



## Our Mission

Medicines for Ireland is an organisation founded and motivated by a strong desire to reform the way Ireland currently procures and supplies medicines. Many of the practices and approaches taken are no longer fit for purpose and are outdated.

Being slow to adopt new medicines; a failure to recognise and work with the new nature of our pharmaceutical market; a lack of coherent data on medicine usage patterns, current and future; and the absence of longer term thinking on medicine needs in the years ahead are just some of the issues Ireland faces.

Globally and in Ireland the presumption of automatic access to innovative medicines is no longer guaranteed. The supply of medicines is an area which requires radical reform to ensure that patients can access life-saving and life-enhancing medicines critical to their well-being.

Achieving reform in this essential area of patient care is a core objective of our organisation.

We are committed to working with key stakeholders to make a positive contribution to deliver change and reforms to support the objective of Irish patients receiving the best medical treatment in the most affordable way.



*founded and motivated by a strong desire to reform the way Ireland's currently procures and supply medicines.*





## About Us

accord

### Accord Healthcare

Accord Healthcare was established in Ireland in 2012 and is one of the fastest growing generic pharmaceutical companies in the country. In early 2017, Accord Ireland merged with Actavis Ireland resulting in a combined extended portfolio of retail and hospital products, along with an exciting pipeline of value-added products and biosimilar medicines for different therapeutic areas.

Accord's Irish office is headquartered at the former Actavis site, Euro House, in Little Island, Cork. It services the sales, marketing, finance, quality, regulatory and business information needs of the business.

Accord Healthcare prides itself on its best-in-market nationwide distribution channels; its ability to adapt to market volatility; its consistency of supply; its ability to supply over 70% of the molecules on the generic interchangeable list; and its quality products.

Approximately 9 million packs of Accord medicine are distributed in Ireland each year. Every 4 seconds a patient somewhere in Ireland takes an Accord medicine. Accord takes this responsibility of providing Irish patients with high quality products very seriously and will continue to offer value, choice, service and support to its range of valued customers across the country into the future.



## Consilient Healthcare

Consilient Health is a privately owned Irish pharmaceutical company specialising in the provision of medicines for therapy areas including women's health, contraceptive care, endocrinology, bone health and obesity. Set up in 2005, Consilient Health partners with leading manufacturers to provide medicines that address patient and healthcare professional needs. We now have operations in Ireland, the UK, the Nordic region and the Gulf territory, with strategic alliances in place in several other territories. The Consilient Health mission is to be a resourceful and trusted partner of choice, delivering quality, reliability and value.



## Clonmel Healthcare

Established in 1970, with in excess of 40 years' experience, Clonmel Healthcare continues to supply an extensive range of medicines to the Irish population through pharmacists, and the medical professions. In addition, the company exports product to several regions within Europe.

Clonmel Healthcare is part of the international global pharmaceutical company STADA AG which employs more than 10,000 people across 22 countries.

Clonmel Healthcare's registered offices are in Clonmel, Co Tipperary. The company currently operates across two locations: administration, logistics, warehousing and regulatory affairs in Clonmel; and sales, marketing and business development in Parkwest, Dublin 12.

Clonmel Healthcare has a number of business divisions in Ireland. Its prescription medicines offer a wide range of generics, branded and hybrid products. In addition, the company has a particular interest with specialised product in the therapeutic areas of neurology, psychiatric, diabetes and osteoporosis.

The company is also a leader in over-the-counter medicines through its business unit established in 2007, specialising in analgesia, mother and baby, and dermatological products. In 2016, Clonmel Healthcare launched its bio-similar division and intends to offer a comprehensive range of product into this space over the next couple of years.

Annually, Clonmel Healthcare places 10.8 million packs of medicine into the Irish market. This makes the company one of the top two suppliers in Ireland.



## Fannin Pharma

Caring for life, at Fannin provides the medical devices, medicines and diagnostic products that help healthcare professionals and patients across the Island of Ireland and the UK manage illness and restore health.

With the heritage of care-giving dating back to 1829, Fannin has the track record to support our claims.

Fannin has a strong history in supply of innovative and quality medicines. Originally focused on the hospital sector we have expanded our business to community pharmacy where we now have a substantial presence.

We provide products across a range of therapeutic areas including respiratory, oncology, haematology, anaesthesia, immunology, and infection control. Our portfolio includes well-established brands together with value-based generic products.

All of the products and services provided by Fannin Pharma are backed up by dedicated support teams including customer service, logistics, quality control, pharmacovigilance and medical information.

DCC Vital Pharma develops, manufactures, markets, sells and distributes a broad range of pharmaceutical products in the UK & Ireland. For our international customer base, we provide contract manufacturing services for oral beta-lactams and also licence-out options on our range of our own developed products. DCC Vital group affiliates include Fannin Limited and Athlone Laboratories in Ireland, as well as Kent Pharmaceuticals in the UK.



## Mylan

Mylan is one of the world's leading global pharmaceutical companies and employs approximately 1,500 people in Ireland. Its medicines include vaccines, medical devices, generics, biosimilars, over-the-counter, and brand-name products. It provides multiple dosage forms, such as difficult-to-manufacture injectables, transdermal patches and HIV/AIDS therapies.

It has innovative research and development capabilities, a robust pipeline, and is one of the world's largest active pharmaceutical ingredient manufacturers. In addition, every one of its medications meets one global quality standard, regardless of where it is produced. Its growing portfolio contains approximately 1,400 products that cover virtually every dosage form and therapeutic category.

The company's workforce is approximately 32,000 people strong. It serves customers in approximately 145 countries and territories. In Ireland, with its manufacturing facilities in Galway and Dublin exporting globally, its Global Respiratory R&D Centre in Dublin, and European Business Centre of Excellence in Dublin, Mylan has deep roots in Ireland and is a proven top employer.



## Pinewood Healthcare

Pinewood Healthcare, established in 1976, is a widely diversified pharmaceutical group presently marketing its products in over 30 countries world-



wide. Pinewood Healthcare is part of Wockhardt International, a global pharmaceutical Company.

With a highly regarded and recognised brand name, Pinewood Healthcare has a strong and unique position in Ireland and the UK, and increasingly in other European and global markets. Pinewood Healthcare is a manufacturer of liquids, creams, ointments, and powders for the pharmaceutical and medical industries.

Pinewood Healthcare has three sales divisions offering products in the following therapeutic areas: antibiotic, cardiovascular, analgesic, dermatological, opioid, gastrointestinal, CNS, rheumatology, hormonal, urological, dietetic, allergy and respiratory.

Pinewood Healthcare has exported worldwide for over 30 years from the manufacturing site in Co. Tipperary, and operates in a first-class internationally recognised facility that offers a professional and quality service to our customers.

Pinewood Healthcare is one of the leading generic pharmaceutical companies in Ireland and as such is proud to offer the medical community throughout the country the choice to prescribe and dispense quality generic treatments at inexpensive prices.

The company markets and distributes a wide range of generic ethical and OTC products direct to retail pharmacies and wholesalers in Ireland from its purpose-built facility in Dublin, ensuring our policy of next-day delivery (same day in Dublin area).

Our Retail & Wholesale division supplies over 5.1 million packs annually to the Irish market.

Pinewood Healthcare has a well-established and dedicated Hospital Pharmacy Sales Division, and is one of the leading generic suppliers of pharmaceuticals to the Irish hospitals market. The company has an extensive hospital product portfolio covering most therapeutic areas, including biosimilar medicines.



## Rowa Pharmaceuticals

Rowa Pharmaceuticals Ltd. was established in Bantry, Co. Cork in 1959 and is currently exporting to over 80 countries worldwide. Today the company employs over 100 people from their base in Bantry, Co. Cork.

Patient welfare, quality and customer focus are the core values of Rowa Pharmaceuticals Ltd. The company is supported by an experienced and highly skilled workforce.

The main manufacturing focuses in Bantry are liquids ointments and creams. Rowa Pharmaceuticals Ltd. production processes are strongly influenced by

the company's German origin. Rowa Pharmaceuticals Ltd. facilities include modern laboratories that meet the highest technological standards, quality assurance procedures, manufacturing, production and packaging facilities, warehouses and storage, administration, export and product marketing.

In 1993, Rowa Pharmaceuticals Ltd. formed a joint venture partnership with Sandoz-Novartis and now today Rowex Ltd. is one of the leading generic companies in Ireland, providing the Irish market with high quality products across a wide range of therapeutic areas including strongly supported OTC brands.



## Teva Pharmaceuticals

Teva Pharmaceuticals Ireland employs over 1,000 people across Ireland, with a number of manufacturing sites and a commercial division in Dundalk.

In 2013, Teva became Ireland's largest generics company (by volume and value) and is also the largest supplier of prescription medicines to Irish patients. Teva now supplies 13% of the total volume prescriptions medicines to the market. Teva places over 13 million packs of medicines on the Irish market each year. Teva's medicine portfolio encompasses a large and growing range of generic medicines together with branded speciality medicines for the treatment of diseases in the areas of central nervous system, cancer, respiratory conditions and pain management.

Teva has an increasing range of biosimilar medicines. In addition, Teva also has a significant over-the-counter medicines range, with many household brands such as Sudocrem, Venos, Infacol, Bisodol.



## Ireland's health landscape

Across the globe, governments are facing the challenge of both providing increased and ever-more complex healthcare services, and funding them.

The increasing demand on services, which has resulted in escalating health-care spending, is being fuelled by common factors: an ageing population; the growing prevalence of chronic diseases and related conditions; the development of life-changing but costly clinical innovations (including new medicines); and rising patient expectations, knowledge and awareness.

The challenges outlined above are equally relevant to Ireland. They increasingly place huge strains on the effective functioning of our health services which struggle to cope with providing and paying for the best and most innovative services and treatments.

Affording our health services now and into the future has become a key consideration for all stakeholders. For the past decade, our health system has struggled and failed to stay within its allocated budget, with supplementary budgets becoming the norm rather than exception. Our health spend has continued to grow and, even with larger budget allocations granted over the past two years, there remains a significant unmet need for services. More innovative, more complex but often more costly treatments are also adding to the financial pressures faced by health providers.

  
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## Spending on healthcare in Ireland

In 2017, the Department of Health's expenditure on health services will be €14.6 billion, representing an increase of almost one billion on current expenditure in 2016. It represents the largest allocation in recent years and is indicative of Ireland's improving economy and a clawback of the major cutbacks imposed during the recession.

Notwithstanding such cutbacks, Ireland's existing spend on healthcare services is already high relative to other countries. When measured by health expenditure per capita, Ireland ranks as the 8th highest spend amongst 35 OECD countries, and the 11th highest in health expenditure expressed as a percentage of GDP<sup>1</sup>. This pattern of an increasing proportion of overall public expenditure funding spent on health services has accelerated in recent years; between 2007 and 2016, total public expenditure on health increased by 9.4%.

While the improving economic conditions in Ireland, in part, explain the willingness of our Government to now increase spending on healthcare, over the longer term increases of this magnitude are unsustainable. This is not least because of the social and demographic changes which are now beginning to impact Ireland, bringing substantial consequences for the delivery of health services in the decades ahead.

**1**  
Health in Ireland Key Trends 2016,  
Department of Health  
<http://health.gov.ie/blog/publications/health-in-ireland-key-trends-2016/>

## The health of the nation

There are numerous reports and research which have all broadly indicated that as a nation, while we are living longer, many people are unhealthier than was the case with previous generations.

Key challenges for the provision of health services in the years ahead include:

### An ageing population:

- Census 2016 data indicates that 18.4% of the population are now 60 years or older. This figure grew by 210,000 between 2006 and 2016 and now stands at 860,000 and is expected to reach 1.15 million by 2026;
- Additionally, the group of individuals aged 80 and over has increased by more than 20,000 between 2006 to 2016 to 68,000, and is expected to reach 104,000 by 2026<sup>2</sup>;
- Life expectancy in Ireland has increased by almost two and a half years since 2005 and has been consistently higher than the EU average throughout the last decade<sup>3</sup>.

**2**  
Census 2016

**3**  
Ibid.



Chronic illness is a major problem for all health systems and are more prevalent as people age. 65% of those over 65 and 80% of those over 85 have two or more chronic conditions<sup>4</sup>.

4

HSE, 2017 Planning for Health, Trends and Priorities to inform Health Service Planning,

- The incidence of chronic diseases in older people is expected to grow by 29% by 2020;
- 58% of Irish adults are classified as either overweight or obese (35% vs 18%)<sup>5</sup>;
- 52.9% of males and 53.5% of females aged 65 and over reported suffering from a chronic illness or health problem<sup>6</sup>.
- In the 75+ age category, 42.8% and 50.2% of males and females respectively reported some or severe limitation in usual activities due to health problems<sup>7</sup>.

5

Ibid.

6

Health in Ireland Key Trends 2016, Department of Health <http://health.gov.ie/blog/publications/health-in-ireland-key-trends-2016/>

7

Ibid.

## Medicine usage and expenditure:

- Total spend on medicine (including fees) in 2015 by the HSE was €2 billion – the largest single item in the healthcare budget;
- The numbers of people on the Long-Term Illness Scheme has increased significantly in recent years and now stands at over 138,000 people<sup>8</sup>, costing €170 million per annum;
- Over 70,000 people avail of the High-Tech Drug Scheme costing €662 million per annum.

8

HSE, Primary Care Reimbursement Service Statistical Analysis of Claims and Payments, 2015


## Health Service Expenditure

- Total public expenditure on health has increased by 9.4% since 2007, with an increase of 4.8% between 2015 and 2016;
- In terms of health expenditure per capita, Ireland ranks as the 8th highest spend amongst selected OECD countries, and 11th highest in health expenditure expressed as a percentage of GDP (35 countries)<sup>9</sup>.


9

Health in Ireland Key Trends 2016, Department of Health <http://health.gov.ie/blog/publications/health-in-ireland-key-trends-2016/>

## The global medicine landscape



*medicines  
are playing  
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As noted above, medicines are playing a larger than ever role in the delivery of effective treatments. While medicines are constantly evolving, so too is the structure of the pharmaceutical industry itself. As noted above, medicines are playing a larger than ever role in the delivery of effective treatments. While medicines are constantly evolving, so too is the structure of the pharmaceutical industry itself.

There has been a significant transformation in the nature and composition of the market. Traditional barriers between branded and generic medicines are becoming less relevant, with most large pharmaceutical companies now having a blend of branded, generic and speciality medicines in their overall portfolio.

Such change requires differing approaches in how all pharmaceutical companies and suppliers engage with policymakers and health funders. Increasingly, too, there is a tension between the positive development of new, more individualised, next-generation medicines that target illnesses once regarded as untreatable, but which are extremely costly to develop, and the ability of Governments and publicly funded health services to pay for these new medicines.

This critical issue of the funding of medicines is an ongoing challenge which will force all stakeholders to adapt and alter current approaches to the provision, supply and funding of medicines. Ensuring continued access to and affordability of medicines for patients presents a big test for all. The growing challenge between patient demands and finite budgets is one which is increasingly becoming a commonplace issue. The recent price negotiations on cystic fibrosis medication highlights the tensions which are now emerging.

## Medicine pricing in Ireland

Against the backdrop of larger numbers of people with chronic diseases and increasing longevity, successive Governments in recent years have sought to contain the price of medicines through using a series of levers. Key amongst these levers have been national medicine pricing agreements and legislative change.

## Pricing agreements

The pricing of medicines in Ireland in recent decades has been determined, to a large degree, through a series of pricing agreements between the Department of Health and the relevant pharmaceutical representative bodies. These agreements have set down medicine prices for a number of years, usually four. Traditionally, agreements have been reached with the Irish Pharmaceutical Healthcare Association (IPHA) negotiated on behalf of proprietary (branded) medicine manufacturers (those still on-patent), followed by a separate agreement negotiated with representatives of the generic medicines sector (off-patent).

## Legislative change

The Health (Supply and Pricing of Medicines) Act 2013 ('2013 Act') legislated for generic substitution and reference pricing. The act changed the way medicines are prescribed and dispensed. Pharmacists now have the power to dispense more affordable generic medicines.

The second key aspect of the legislation was the introduction of reference pricing of medicines by the HSE. This reference pricing of medicines has benchmarked Irish prices against a basket of comparable European states.

The result of both initiatives has been a significant increase in the usage of generic medicines in Ireland, with the volume of those used growing from 11% pre-2013 to 53% of all off-patent medicines by 2016. At the same time, by switching to more affordable medicines, the state has saved hundreds of millions in the almost four years since the legislation's introduction.

## Continuing reform

While the 2013 Act represented a watershed moment in Ireland's medicine supply policy and delivered meaningful reform, there remains much more work to do in this area.

The 2013 Act proved the value of reform, particularly the monetary savings which can be achieved if all players are committed to carrying through such reforms.

The membership of Medicines for Ireland played a key role in delivering the reforms of recent years. Our respective companies have been to the fore in the manufacture and supply of innovative, often more affordable medicines.



*Pharmacists  
now have  
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generic  
medicines.*





*It is critical  
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We are eager to continue this reform agenda to ensure that access to the most advanced medicines and treatments continue to be available to Irish patients, despite the ongoing funding challenges which our health service faces.

Continuing the reform agenda is the only way to guarantee such access. It is critical that reforms deliver cost savings which can be reinvested into other areas of our health services, including new medicines.

While medicine reforms introduced in Ireland in recent years are welcome, most, such as generic substitution, have been the norm and standard practice in most EU states for many years. In Ireland, we have been slow to adopt reforms which are commonplace across other health systems. Maintaining the reform momentum is crucial.

Medicines for Ireland is a key supplier of medicines and associated services to our health services. Each day we engage with a broad range of stakeholders – patients, policymakers, pharmacists, health managers, physicians, procurement officers etc.

This engagement gives us a unique insight into how medicine procurement in Ireland currently operates and where further reforms are needed.

Equally, the multi-national reach of our member companies arms us with knowledge and experience of examples of best practices and successful reforms implemented across the globe—innovations, which we believe, can be introduced to enhance Ireland's healthcare services.

As an organisation, our objective is to contribute to the reform of our health service and to have a positive impact in bringing forward policy proposals to achieve this objective. On this basis, set out below are our key reform proposals.

We believe that if introduced, these reforms will expand patient access to medicines, improve affordability and deliver savings for payers and patients.





# Medicines for Ireland reform proposals

## 1. National Medicines Strategy

Medicines are today playing a greater role than ever before in allowing patients to lead healthier, longer lives. In addition to treating more common conditions such as heart disease or cancer, medicines are becoming increasingly specialised and treating more niche illnesses. As medicine becomes more personalised to each individual, this trend looks set to continue, with the importance of medicines in our daily lives growing.

Despite the importance of medicines to the wellbeing of patients and the successful treatment and management of the majority of medical conditions, Ireland does not have a national medicines strategy.

With our national spend on medicine likely to grow, and grow contentious, it is now time to develop such a strategy. A strategy is needed to provide a blue-print for the long-term procurement, supply and usage of medicines in Ireland. It will also be a vital roadmap in guiding policymakers and healthcare professionals in the management and optimal usage of medicines across all healthcare settings.



*A strategy  
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### Reform proposal: National Medicines Strategy

Key aspects of the strategy include:

- The development of a long-term strategy which will guide the regulation, procurement and management of the use of medicines across our health services;
- Identification of the strategies needed to meet these objectives and the stakeholders responsible for implementing this strategy;
- Undertake a review of the current national structures which are involved in all areas of the supply of medicines to ensure that these structures and the approach taken is joined-up, streamlined and achieves the best value for money; and
- Establish a new National Medicines Office to coordinate all aspects of medicine supply and pricing in Ireland and implement this strategy. See below for more information on this proposal.

## 2. Establishment of National Medicines Office



*medicines  
now account  
for over 18%  
of total health  
budget.*



Like all developed economies, Ireland's healthcare system and the health of its people is very dependent on medicines. Advances in medical treatments have made medicines more important than ever before in the care of patients.

However, as treatments have advanced and become more sophisticated, their price has grown too. Decision-makers are often torn between the cost of these treatments and how to fund them, and the genuine demands and needs for these treatments from patients.

The capacity for Government to fund next-generation medicine treatments is now a critical issue in Ireland. With an annual spend of over €2 billion per annum on medicines, they now account for over 18% of total health budget.

The supply of medicines from manufacturer to healthcare professional, and ultimately to patients, is complex. While there are many layers before the end user receives a medicine, the funding of medicines is equally complex. The majority of the cost of medicines is funded by the state Primary Care Reimbursement Service (PCRS) through either one of the four publicly funded schemes: the General Medicine Scheme (GMS), Drugs Payment Scheme (DPS), Long-term Illness Scheme (LTI) or High-Tech Drugs Scheme (HTD).

Beyond the PCRS division, within the HSE there are various other units/bodies even within the Health Service Executive and Department of Health dealing with other aspects of medicines supply and delivery such as the Corporate Pharmaceutical Unit (CPU), the Medicine Management Programme and National Drugs Management Scheme. Separately, hospitals determine and locally manage their own medicine supply and procurement policies.

While these bodies work diligently in the interests of their own area of responsibility, there is no specialised unit working to strategically develop medicine policy, to evaluate current approaches and ensure that they are fit for purpose, including ensuring best value for the state, or to raise awareness amongst physicians and patients about new or more affordable medicines. A coordinated body to oversee all aspects of our medicine strategy is now essential.

Reform proposal: The establishment of a new National Medicines Office within the HSE.

The office would merge the existing myriad of bodies that deal with medicine supply and pricing within our health service including the CPU and PCRS.

This new office would be tasked with:

- Developing and implementing strategic policy to support the provision of medicines to Irish patients;
- Developing policy proposals on current and future access to medicines and funding for medicines;
- Anticipating emerging medicine shortage issues and addressing such shortages in a timely way;
- Evaluating both current and future supply and the funding of medicines provided to Irish patients to include issues such as prescribing and dispensing trends, medicine prices and costs, volumes and usage and patient profiles;
- Oversee and develop new and existing medicine management programmes such as the National Drugs Management Scheme;



*The supply of medicines from manufacturer to healthcare professional, and ultimately to patients, is complex.*



*A co-ordinated body to oversee all aspects of our medicine strategy is now essential.*



- Leading on the negotiation of any future medicine pricing agreements with pharmaceutical companies;
- Playing a central role in developing and implementing medicine information and awareness campaigns for the benefit of health care professionals, patients and their advocates, policy officials, Government and elected representatives and the wider public.

### 3. New national medicine pricing agreement

*The traditional boundaries between branded and generic companies are increasingly irrelevant, with pharmaceutical companies having both types of medicines.*

As noted above, the nature of the pharmaceutical industry globally and in Ireland has changed dramatically in recent years. The traditional boundaries between branded and generic companies are increasingly irrelevant, with pharmaceutical companies having both types of medicines. Furthermore, as mergers between pharmaceutical companies gather pace, with larger entities now being the norm, this mixture of medicine types further breaks down distinctions of the past.

This state of affairs glaringly highlights the inadequacies of the manner in which Ireland approaches its medicine pricing agreements and wider negotiations process around it. Currently, the Department of Health concludes four-year pricing agreements with the Irish Pharmaceutical Healthcare Association (IPHA) which deals with on-patent medicines. Once this agreement has been concluded, the Department of Health then moves to reach agreement with representatives of the generics industry.

This method of negotiation is outdated and irrelevant. It fails to recognise that the divisions between branded and generic companies, which the Department of Health, through its negotiating approach perceives to exist, are increasingly obsolete.

Worse, it can often result in a bad deal for the state and ultimately taxpayers. By failing to have **all** pharmaceutical companies around the negotiating table, the downward pressure on medicine prices which the existence of competing interests could have is lost. This fact is borne out nowhere more clearly than through the presence of a clause in the Department of Health's most recent pricing agreement with the IPHA from July 2016, which functions as a disincentive to biosimilars entering the market. This clause protects the position of the more expensive biologic medicines in the face of competition from more affordable biosimilar medicines, despite the growing move toward biosimilars across the world. Our patients, health services and taxpayers are the losers.

As discussed further in this document, elements of these pricing agreements, such as the lack of pricing flexibility for high-volume, low-value medicines, are often also leading to prolonged medicine shortages.



## New approach to medicine pricing agreement

We recommend a new medicine pricing agreement structure which encompasses a transparent, inclusive roundtable negotiating approach where all the pharmaceutical interests are represented at all talks, and which take place at the same time.

This contrasts directly with the current approach of creating a 'false' division between so-called branded and generic companies.

Key components of this new approach to pricing agreements would include:

- Representatives from all sectors in the pharma supply chain represented;
- All pharmaceutical manufacturer representatives at the talks table, at the same time;
- Negotiations led by the National Medicines Office (see above);
- Greater transparency on the rationale for decisions arrived at;
- Availability of greater information on the nature and source/s of savings to be achieved over the lifetime of any pricing agreements;
- Ongoing monitoring of the terms and implementation of all agreements by the newly created National Medicines Office; and
- Publication by the office of a 6-monthly agreement tracker which sets out savings realised under the Agreement and the sources of same.



*We re-commend a new medicine pricing agreement structure which encompasses a transparent, inclusive roundtable negotiating approach*



## 4. Increase usage of biosimilar medicines



*biosimilars have been proven to be as safe and effective as original 'biological' drug and generally cost significantly less,*



### **What are biologics?**

A biologic is a medicine that contains an active substance made by a biological process or derived from a biological source.

Biological products are used for a wide range of diseases and conditions, including serious and life-threatening conditions such as cancers and rheumatoid arthritis.

### **What are biosimilars?**

As the name suggests, biosimilars are similar but not identical versions of the equivalent biological medicine.

However, biosimilars have been proven to be as safe and effective as original 'biological' drugs and generally cost significantly less, adding up to significant savings for healthcare systems.

Biosimilars were first authorised by the European Medicines Agency for use in Europe in 2007. There are now 28 biosimilars authorised for use and this number is expected to grow as growing number of biologics come off-patent in the years to come. A further €62 billion worth of biologic medicines are expected to go off patent by 2020.

Across Europe, biosimilars have grown in prominence and are now a standard part of treatment regimes. Biosimilar medicines are recognised as improving functional and clinical outcomes, and are welcomed as a means to control the significant cost of biological medicines.



*the uptake and volume of such medicines being used across the Irish healthcare service remains critically low.*



### **Low uptake of biosimilars in Ireland – the missed opportunity**

Ireland lags significantly behind other European countries in its usage of biosimilars with only 11 currently reimbursed by the HSE, out of a total of 28 authorised for use in the EU (see chart).

Even in circumstances where the biosimilar is available to Irish patients, the uptake and volume of such medicines being used across the Irish healthcare service remains critically low.

A striking example of this situation in Ireland lies in the usage of the biosimilar Benepali (biologic Enbrel), used to treat various forms of arthritis.

Despite its potentially huge cost saving, since its introduction to Ireland in August 2016, only 54 packets of the drug were sold compared to almost 46,856 of the established rival brand (as of May 2017). It is discouraging other biosimilars from launching in Ireland, with the net result that competition in this sector of the medicine market will either diminish or not take place.

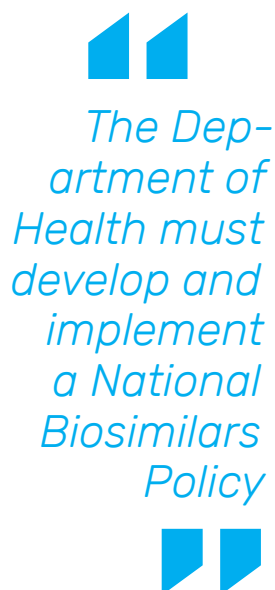
	Biosimilar	Condition	Available in Ireland	Reimbursed by HSE	High Tech Scheme
1	Abasaglar (previously Abasria)	Diabetes	✓	✓	✗
2	Abseamed	Anaemia, Cancer, Chronic kidney failure	✓	✗	✗
3	Accofil	Neutropenia	✓	✓	✓
4	Amgevita	Arthritis, Juvenile rheumatoid arthritis, Psoriatic arthritis, Rheumatoid colitis, Ulcerative crohn's disease, Psoriasis, Ankylosing spondylitis	✓	✗	✗
5	Bemfola	Anovulation (IVF)	✓	✓	✓
6	Benepali	Axial spondyloarthritis, Psoriatic arthritis, Plaque psoriasis, Rheumatoid arthritis	✓	✓	✓
7	Binocrit	Anaemia, Chronic kidney failure	✓	✗	✗
8	Epoetin alfa Hexal	Anaemia, Cancer, Chronic kidney failure	✓	✗	✗
9	Filgrastim Hexal	Cancer, Haematopoietic stem cell transplantation, Neutropenia	✓	✗	✗
10	Flixabi	Ankylosing spondylitis, Crohn's disease, Psoriatic arthritis, Psoriasis, Rheumatoid arthritis, Ulcerative colitis	✓	✗	✗
11	Grastofil	Neutropenia	✓	✓	✓
12	Inflectra	Ankylosing spondylitis, Crohn's disease, Psoriatic arthritis, Psoriasis, Rheumatoid arthritis, Ulcerative colitis	✓	✗	✗
13	Inhixa	Venous Thromboembolism	✓	✗	✗
14	Lusduna	Diabetes Mellitus	✓	✗	✗
15	Movymia	Osteoporosis	✓	✗	✗
16	Nivestim	Cancer, Haematopoietic stem cell transplantation, Neutropenia	✓	✓	✓
17	Omnitrope	Pituitary dwarfism, Prader-Willi syndrome, Turner syndrome	✓	✓	✓
18	Ovaleap	Anovulation (IVF)	✓	✗	✗
19	Ratiograstim	Cancer, Haematopoietic stem cell transplantation, Neutropenia	✓	✓	✓
20	Remsima	Ankylosing spondylitis, Crohn's disease, Psoriatic arthritis, Psoriasis, Rheumatoid arthritis, Ulcerative colitis	✓	✗	✗
21	Retacrit	Anaemia, Autologous blood transfusion, Cancer, Chronic kidney failure	✓	✓	✓
22	Silapo	Anaemia, Autologous blood transfusion, Cancer, Chronic kidney failure	✓	✗	✗
23	Solymbic	Arthritis, Psoriatic arthritis, Rheumatoid colitis, Ulcerative crohn's disease, Hidradenitis suppurativa, Psoriasis, Ankylosing spondylitis	✓	✗	✗
24	Terrosa	Osteoporosis	✓	✗	✗
25	Tevagrastim	Cancer, Haematopoietic stem cell transplantation, Neutropenia	✓	✓	✓
26	Thorinane	Venous Thromboembolism	✓	✗	✗
27	Truxima	Arthritis, Rheumatoid arthritis, B-cell chronic lymphocytic leukaemia, Non-Hodgkin lymphoma, Microscopic polyangiitis, Wegener granulomatosis	✓	✗	✗
28	Zarzio	Cancer, Haematopoietic stem cell transplantation, Neutropenia	✓	✓	✓

TABLE 1: AVAILABILITY AND REIMBURSEMENT STATUS OF APPROVED BIOSIMILARS IN IRELAND.

There are currently a number of barriers blocking the wider introduction of biosimilars in Irish healthcare. These include:

- Legislation which explicitly prohibits biosimilars from being placed on the interchangeable list of medicines;
- The presence of a clause in the Department of Health's own medicine pricing agreement with IPHA (2016 – 2020), which makes it extremely difficult for biosimilars to enter the Irish market; and
- There is no incentive or disincentive for a prescriber to use a biosimilar, or any cost effective medicines, in the High Tech Scheme.
- A chronic lack of information for patients and healthcare professionals on biosimilars on their safety, efficacy and cost saving potential;

#### Reform proposal: Activation of National Biosimilars Policy



The Department of Health must develop and implement a National Biosimilars Policy, whose objective is to significantly increase the usage of biosimilars in Ireland within 5 years.

This policy must include:

- Legislation which reforms the 2013 Act and allows for biosimilars to be included on the list of interchangeable medicines;
- The Department of Health must immediately remove the existing biosimilar blocker clause contained within the Medicine Pricing Agreement with IPHA to ensure genuine competition between biosimilars and biologics;
- The HSE must introduce quotas for the usage of biosimilars in each hospital; and
- The Department of Health and HSE, supported by representative bodies such as Medicines for Ireland, must activate an extensive information campaign on biosimilars.

## 5. Increase levels of cost-effective prescribing for non-interchangeable and high-tech medicines

What are non-interchangeable medicines? Within the 2013 Act, there are four very broad categories of medicines and/or medical devices that are prohibited from being added to the interchangeable list of medicines. Included in these are biologic medicines, inhaler devices and medicines with two or more active ingredients.

The rationale for the prohibition on adding these wide categories of medicines to the interchangeable list needs to be reviewed in conjunction with HPRA and vis-à-vis best practice in other comparable markets. Science changes at incredible pace; therefore some of the parameters which the legislation intended to safeguard, like patient safety, have changed as new evidence has come to light since its drafting almost five years ago.

Furthermore, without generic substitution, there is nothing to entice competition to the Irish market. Prescribers are not focused on the cost of medicines and indeed are often unaware of how much a medicine, particularly a high-tech medicine, costs the state. Without some intervention on the part of the payer, either through indicative drug budgeting or an alternative instrument, it is difficult to envisage how competition will come to the market and therefore, how savings in this space will be generated.

As a specific example, and leaving aside biosimilar opportunities for creating budgetary space, over €20m of chemical medicines have lost patent exclusivity in the past three years.

These six medicines are reimbursed under the High-Tech Scheme. Generics have entered the market, offering 60% savings to the state. However, generic uptake remains at below 20% on average. If this was increased to the current average generic uptake of 53%, savings to the state would amount to over €6m per year.

### Reform proposal: Non-Interchangeable Medicines

#### Reform Proposal: Non-Interchangeable Medicines

- Review criteria for non-inclusion of medicines to the Interchangeable List;
- Consider indicative drug budgeting scheme which encourages and incentivises prescribers for making cost-effective prescribing decisions;
- Expedite the addition of chemically based off-patent medicines that fall within the High-Tech Scheme to the Interchangeable List.



*some of the parameters which the legislation intended to safeguard, like patient safety, have changed as new evidence has come to light since its drafting almost five years ago.*





## 6. Tackling growing medicine shortages

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Clanwilliam Survey of Pharmacist, July 2016 - <http://www.clanwilliamgroup.com/press-releases/2016/07/18/more-than-90-per-cent-of-community-pharmacists-say-medication-shortages-are-getting-worse/>

Medicine shortages in Ireland are becoming an increasing problem. A survey of pharmacists in 2016 found that 90% of pharmacists experienced shortages. In recent years there have been acute shortages in sourcing medicines for commonplace conditions, such as those used to treat thyroid conditions and hormone replacement therapy (HRT).

The impact of medicine shortages is felt across the healthcare service, with patients most directly affected. Beyond the potentially severe health consequences of such shortages, there are also other negative effects. In many cases, the HSE has been forced to pay multiples of the original cost of the medicines in order to source alternatives. Recent shortages have included injectable medicines to treat cancer and injectable antibiotics.

In addition to the high costs forced upon the HSE, often these medicines are unlicensed given the emergency nature of the situation. Such unlicensed medicines would not be permitted in usual circumstances.

The reasons why shortages of medicines occur can be varied and include manufacturing issues, product recalls, spikes in demand, pricing issues which make it uneconomical to supply the relatively small Irish market, or parallel exporting whereby medicines are exported out of Ireland to higher medicine cost economies.


The segment of medicines most impacted by shortages tends to be the low-value medicine market. These medicines, which the HSE spends up to €200 million per annum, typically cost less than €2 million a year per medicine type. However, cumulatively they account for up to 15% of the total medicine budget.

Why shortages are common in this grouping is due to the fact that often there is no competition for these medicines in the Irish market, with a single manufacturer supplying the HSE. Often there is also no generic alternative. When this supplier encounters a difficulty in supplying, there is no one else in the market capable of stepping in to fill the gap.


The fact that there is no generic alternative available is linked to the fact that the price entry point is so low as to dissuade generic competition from entering the market. This is outlined in greater detail below.

Under the terms of the current Medicine Pricing Agreement 2016, the price of a generic low-value medicine must be 40% lower than the branded medicine once the patent falls on the latter. This acts as a direct disincentive to generic competition entering the Irish market and thereby ensuring that the likelihood of shortages is significantly reduced.

This one-size-fits-all approach does not reflect the reality of the situation and does not help to tackle shortages and, more importantly, to prevent them from occurring. Greater flexibility is required.




*This one-size-fits-all approach does not reflect the reality of the situation*




## Reform proposal: Medicine shortages

- The Hardship Scheme needs to be revitalised and price increases for older and inexpensive medicines needs to form part of the National Medicines Strategy;
- Price entry point for generics entering market with low value or low volume medicines needs to be revisited in order to attract competition and enhance security of supply;
- Allow for a reduction in HPRA fees for batch specific variations which can be used to relieve shortages in the Irish market by using medicines approved for sale in other EU jurisdictions.



*price  
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Strategy.*



# Safeguarding medicine quality and efficacy

## Falsified Medicines Directive and the Irish Medicines Verification Organisation



*Medicines for Ireland fully supports the implementation in Ireland of the EU Directive on Falsified Medicines.*



Medicines for Ireland fully supports the implementation in Ireland of the EU Directive on Falsified Medicines (2011/62/EU). The Directive's objective is to tackle the growing problem of false or counterfeit medicine entering the legitimate medicines supply chain. The directive states that each eligible medicinal product must have a unique identifier and tamper-evident seal to allow for the verification of each medicine pack at the point of dispensing.

This verification system must be fully in place by February 2019. Each EU member state must have a single national body to oversee and implement the terms of the directive in Ireland. In Ireland, this organisation is the Irish Medicines Verification Organisation (IMVO). IMVO has been established through a collaboration between relevant stakeholders in the Irish prescription medicines supply chain.

Medicines for Ireland has been actively involved in the development of IMVO and is extremely committed to ensuring that this system of verification is successfully implemented by the 2019 deadline.

We believe that its implementation will ensure patients are better protected against counterfeit medicines through enhanced traceability and stronger verification processes.



## Opportunities for further growth

The pharmaceutical industry is a dynamic and rapidly changing one. Yet Ireland cannot afford to become complacent about our success to date.

While we believe that there remains significant opportunities for Ireland's pharmaceutical industry to grow further, Ireland is now a global player constantly competing with other countries to secure new inward investment from multinationals. Constant innovation and policy responsiveness to the needs of industry remains critical.

In terms of further growth opportunities for the industry here, the current EU regime of Supplementary Protection Certificates (SPCs) actively impedes the growth of additional pharmaceutical manufacturing in Ireland.

### Supplementary Protection Certificate

A Supplementary Protection Certificate (SPC) extends the protection of patented medicines by up to five years to compensate the time lost in obtaining regulatory approval of the medicine.

During this period, European manufacturers of generic and biosimilar medicines cannot produce their medicines in the EU. This situation prevents EU-based manufacturers from producing medicines for regions outside the EU during the period of the SPC, despite the fact that the SPC protection does not exist in many regions—Canada, Brazil, Russia, India and China—or is less than five years in others.



*Ireland  
cannot afford  
to become  
complacent  
about our  
success to  
date.*





*EU reliance  
on foreign  
manu-  
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jobs in the EU,*



The unintended consequence of the SPC regulation is that it prevents EU-based generic manufacturers from producing during the period of SPC protection of the reference medicine for export to unprotected markets. In particular, this situation prejudices competitiveness of EU companies in the US market, where patents and patent extensions will, in most cases, expire earlier than in the EU due to the more rapid introduction of new medicines. This is the case with major biological products, as well as chemical molecule products.

In addition, this situation gives an unintended lead time advantage to non-EU based operators as regards entering EU member states' generics market immediately upon the SPC protection expiry.

This forces European manufacturers of generic and biosimilar medicines to move their production outside the EU—either via delocalisation or long-term outsourcing contracts (often the only option for SMEs)—to overcome these legal hurdles and to stay globally competitive. EU reliance on foreign-manufactured medicines might be increasing, with the loss of high-value jobs in the EU, including Ireland.

## The solution – an SPC manufacturing waiver

An SPC manufacturing waiver would overcome the current barriers by allowing generic and biosimilar manufacturers based in the EU to produce medicines during the SPC protection period to supply unprotected markets as soon as permitted. Such a waiver would not threaten or undermine the SPC system as it currently operates in the EU. The SPC waiver would only allow EU generic and biosimilar industries to be market ready once all protections expire. They would also allow these manufacturers to produce medicines within the EU, as opposed to outside of it as currently happens.

We strongly believe that such a reform would assist in attracting more R&D and manufacturing activity into the EU than is currently the case.

## Current status of SPC manufacturing waiver

On 28 October 2015, the European Commission published a position paper in which it examined a proposal for an SPC manufacturing waiver, recognising its potential to create new high-skill pharmaceutical jobs and stimulate economic growth in the EU. In February 2017, the Commission published an impact assessment, followed up by a public consultation on the issue. The Commission has committed to publishing a final impact statement on the



issue by Q4 2017. Both the European Parliament and Council have signalled their support for the SPC manufacturing waiver.

## The opportunity for Ireland

The introduction of a waiver could substantially benefit Ireland. We already enjoy a vibrant and internationally recognised pharmaceutical manufacturing sector, including a strong generic and biosimilar manufacturing base. The waiver offers Ireland the opportunity to attract further investment and manufacturing jobs.

Reform proposal: The Irish Government at EU level must push strongly for the Commission to introduce regulation to implement the SPC manufacturing waiver. Equally, we urge Ireland's MEPs, North and South, to continue to advocate in favour for the implementation of the waiver.



*The waiver offers Ireland the opportunity to attract further investment and manufacturing jobs.*



## Irish Pharmaceutical industry and Brexit

We recognise the fundamentally critical role that the Industrial Development Authority (IDA) has played in developing Ireland as a global leader in pharmaceutical manufacturing. Through the decades, they have provided invaluable support and expertise to new pharma companies, including Medicines for Ireland members, establishing and expanding in Ireland. In a post-Brexit Ireland, the contribution of the IDA in sustaining Ireland's economic recovery will be even more vital.

Reform proposal: As Ireland prepares for the negative impacts and opportunities presented by Brexit ensuring that IDA Ireland is sufficiently resourced to meet these challenges is essential. For the pharmaceutical sector IDA support services in the areas of R&D, training, employment and capital expenditure are particularly important.



*In a post-Brexit Ireland, the contribution of the IDA in sustaining Ireland's economic recovery will be even more vital.*







